

APPLICATION NO.

10/087,714

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Daphna Havkin-Frenkel	DMCI-0099	7483
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ART UNIT

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)		
	10/087,714	HAVKIN-FRENKEL ET AL.		
Office Action Summary	Examiner	Art Unit		
	Cynthia Collins	1638		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a repl If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute  - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	36(a). In no event, however, may a reply be time y within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).		
1) Responsive to communication(s) filed on				
2a) This action is <b>FINAL</b> . 2b) This	action is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4) Claim(s) is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-31 are subject to restriction and/or election requirement.				
Application Papers				
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>				
Priority under 35 U.S.C. §§ 119 and 120				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. <ol> <li>a) The translation of the foreign language provisional application has been received.</li> </ol> </li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.</li> </ul>				
Attachment(s)				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 Notice of Informal Pa	PTO-413) Paper No(s) atent Application (PTO-152)		

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a method for improving production of vanillin in cultured *Vanilla planifolia* by supplementing tissue culture with compounds, and to cultured *Vanilla planifolia* cells, classified in class 435, subclass 430.1, for example.
- II. Claims 11-15, drawn to a method for improving production of vanillin in cultured Vanilla planifolia by subjecting the culture to a stress condition, and to cultured Vanilla planifolia cells, classified in class 435, subclass 430.1, for example.
- III. Claims 16-25, drawn to a method for improving production of vanillin in cultured Vanilla planifolia which comprises genetically engineering the cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, wherein the enzyme is associated with chain shortening of p-coumaric acid to p-hydroxybenzaldehyde, and to genetically engineered Vanilla planifolia cells and plants, classified in class 800, subclass 298, for example.
- IV. Claims 16 and 20-25, drawn to a method for improving production of vanillin in cultured *Vanilla planifolia* which comprises genetically engineering the cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, wherein the enzyme is associated with chain shortening of ferulic acid to vanillin, and to genetically engineered *Vanilla planifolia* cells and plants, classified in class 435, subclass 419, for example.

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- V. Claims 16-17 and 20-25, drawn to a method for improving production of vanillin in cultured *Vanilla planifolia* which comprises genetically engineering the cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, wherein the enzyme is associated with hydroxylation of phydroxybenzyl alcohol to 3,4-dihydroxybenzyl alcohol or aldehyde, and to genetically engineered *Vanilla planifolia* cells and plants, classified in class 435, subclass 419, for example.
- VI. Claims 16-17 and 20-25, drawn to a method for improving production of vanillin in cultured *Vanilla planifolia* which comprises genetically engineering the cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, wherein the enzyme is associated with methylation of 3,4-dihydroxybenzaldehyde to vanillin, and to genetically engineered *Vanilla planifolia* cells and plants, classified in class 435, subclass 468, for example.
- VII. Claims 26 and 29, drawn to a method for improving vanillin accumulation in cultured *Vanilla planifolia* which comprises inhibiting the production or activity of vanillyl alcohol dehydrogenase by treating the cells with an inhibitor, classified in class 435, subclass 430.1, for example.
- VIII. Claims 26-28, drawn to a method for improving vanillin accumulation in cultured *Vanilla planifolia* which comprises inhibiting the production or activity of vanillyl alcohol dehydrogenase by genetically engineering the cells, and to a genetically engineered *Vanilla planifolia* cell, classified in class 800, subclass 285, for example.

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- IX. Claims 30-31, drawn to a method for improving production of vanillin in cultured *Vanilla planifolia* which comprises genetically engineering the cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, wherein the enzyme is associated with chain shortening of p-coumaric acid to p-hydroxybenzaldehyde, and inhibiting the production or activity of vanillyl alcohol dehydrogenase, and to a *Vanilla planifolia* cell, classified in class 435, subclass 419, for example.
- X. Claims 30-31, drawn to a method for improving production of vanillin in cultured Vanilla planifolia which comprises genetically engineering the cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, wherein the enzyme is associated with chain shortening of ferulic acid to vanillin, and inhibiting the production or activity of vanillyl alcohol dehydrogenase, and to a Vanilla planifolia cell, classified in class 435, subclass 468, for example.
- XI. Claims 30-31, drawn to a method for improving production of vanillin in cultured *Vanilla planifolia* which comprises genetically engineering the cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, wherein the enzyme is associated with hydroxylation of phydroxybenzyl alcohol to 3,4-dihydroxybenzyl alcohol or aldehyde, and inhibiting the production or activity of vanillyl alcohol dehydrogenase, and to a *Vanilla planifolia* cell, classified in class 435, subclass 419, for example.

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XII. Claims 30-31, drawn to a method for improving production of vanillin in cultured Vanilla planifolia which comprises genetically engineering the cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, wherein the enzyme is associated with methylation of 3,4-dihydroxybenzaldehyde to vanillin, and inhibiting the production or activity of vanillyl alcohol dehydrogenase, and to a Vanilla planifolia cell, classified in class 435, subclass 468, for example.

Claim 16 link(s) inventions III-VI. Claim 26 link(s) inventions VII-VIII. Claim 30 link(s) inventions IX-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 16, 26, or 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re*Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions I-XII are distinct methods that result in the production of distinct products. The method of invention I requires supplementing tissue culture with compounds, which is not required by the methods of inventions II-XII. The method of invention I does not require subjecting cultured *Vanilla planifolia* cells to a stress condition, which is required by the method of invention II. The method of invention I also does not require inhibiting the production or activity of vanillyl alcohol dehydrogenase by treating the cells with an inhibitor, which is required by the method of invention VII. The method of invention I additionally does not require the genetic engineering of *Vanilla planifolia* cells, as is required by the methods of inventions III-VI and VIII-XII.

Inventions II-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions II-XII are distinct methods that result in the production of distinct products. The method of invention II requires subjecting cultured *Vanilla planifolia* cells to a stress condition, which is not required by the methods of inventions III-XII. The method of invention II does not require inhibiting the production or activity of vanillyl alcohol dehydrogenase by treating the cells with an inhibitor, which is required by the method of

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invention VII. The method of invention II also does not require the genetic engineering of *Vanilla planifolia* cells, as is required by the methods of inventions III-VI and VIII-XII.

Inventions III-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions III-XII are distinct methods that result in the production of distinct products. The method of invention III requires genetically engineering cells to overproduce one or more enzymes associated with chain shortening of p-coumaric acid to p-hydroxybenzaldehyde, which is not required by the methods of inventions IV-VIII and X-XII. The method of invention III also does not require inhibiting the production or activity of vanillyl alcohol dehydrogenase, which is required by the method of invention IX.

Inventions IV-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions IV-XII are distinct methods that result in the production of distinct products. The method of invention IV requires genetically engineering the cells to overproduce one or more enzymes associated with chain shortening of ferulic acid to vanillin, which is not required by the methods of inventions V-IX and XI-XII. The method of invention IV also does not require inhibiting the production or activity of vanillyl alcohol dehydrogenase, which is required by the method of invention X.

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Inventions V-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions V-XII are distinct methods that result in the production of distinct products. The method of invention V requires genetically engineering cells to overproduce one or more enzymes associated with hydroxylation of p-hydroxybenzyl alcohol to 3,4-dihydroxybenzyl alcohol or aldehyde, which is not required by the methods of inventions VI-X or XII. The method of invention V also does not require inhibiting the production or activity of vanillyl alcohol dehydrogenase, which is required by the method of invention XI.

Inventions VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions VI-XII are distinct methods that result in the production of distinct products. The method of invention VI requires genetically engineering cells to overproduce one or more enzymes associated with methylation of 3,4-dihydroxybenzaldehyde to vanillin, which is not required by the methods of inventions VII-XI. The method of invention VI also does not require inhibiting the production or activity of vanillyl alcohol dehydrogenase, which is required by the method of invention XII.

Inventions VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions VII-XII are distinct methods that result in the production of distinct products. The method of invention VII requires inhibiting the production or activity of vanillyl alcohol dehydrogenase by treating the cells with an inhibitor, which is not required by the methods of inventions VIII-XII. The method of invention VII also does not require the genetic engineering of *Vanilla planifolia* cells, as is required by the methods of inventions VIII-XII.

Inventions VIII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions VIII-XII are distinct methods that result in the production of distinct products. The method of invention VIII does not require genetically engineering cells to overproduce one or more enzymes associated with one or more steps of vanillin biosynthesis, as is required by the methods of inventions IX-XII.

Inventions IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions IX-XII are distinct methods that result in the production of distinct products. The method of invention IX requires genetically engineering cells to

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overproduce one or more enzymes associated with chain shortening of p-coumaric acid to p-hydroxybenzaldehyde, which is not required by the methods of inventions X-XII.

Inventions X-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions X-XII are distinct methods that result in the production of distinct products. The method of invention X requires genetically engineering cells to overproduce one or more enzymes associated with associated with chain shortening of ferulic acid to vanillin, which is not required by the methods of inventions XI-XII.

Inventions XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The methods of inventions XI-XII are distinct methods that result in the production of distinct products. The method of invention XI requires genetically engineering cells to overproduce one or more enzymes associated with hydroxylation of p-hydroxybenzyl alcohol to 3,4-dihydroxybenzyl alcohol or aldehyde, which is not required by the method of invention XII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and the requirement for different areas of search, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC 12/2/03

ASHWIN D. MEHTA, PH.D.